UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
FORT WAYNE DIVISION

CYNTHIA ANN WARNER-BORKENSTEIN and DAVID BORKENSTEIN Plaintiffs v. AMERICAN MEDICAL SYSTEMS, INC. *et al.* Defendants	CAUSE NO. 1:19cv255 DRL-SLC

OPINION AND ORDER

This case has evolved to a second amended complaint that the medical device defendants have now moved to dismiss under Federal Rule of Civil Procedure 12(b)(6). The Borkensteins claim that the MiniArc® mesh sling manufactured, designed, and sold by the defendants caused Ms. Cynthia Ann Warner-Borkenstein injuries and required revisional surgery. The defense argues that the second amended complaint remains deficient by not alleging a specific defect or otherwise meeting federal pleading standards, in particular under a manufacturing defect theory, and that the Borkensteins have pleaded claims that are not cognizable or are subsumed within the Indiana Product Liability Act, leaving but derivative allegations that cannot stand on their own. The court grants the motion to dismiss—but only in part.

BACKGROUND

Taking the second amended complaint's allegations as true, as the court must at this stage, the following facts for purposes of this motion emerge. The Borkensteins allege that the slate of defendants designed, manufactured, labeled, and sold the MiniArc. ECF 34 ¶ 10. Designed it seems to treat pelvic organ prolapse, the MiniArc received federal approval for its marketing from the Food and Drug Administration. *Id.* ¶ 21.

In October 2013, Ms. Warner-Borkenstein underwent surgery at Dupont Hospital in Fort Wayne, Indiana during which the surgeon implanted a MiniArc. *Id.* ¶ 15. The Borkensteins have alleged the product's reference number and lot number as reflected in the operative report, which in this court's experience aids the defense in identifying manufacturing and other records related to this specific product. *Id.* After the implant, Ms. Warner-Borkenstein experienced severe pelvic pain, mesh exposure, urinary incontinence, and other complications from the device. *Id.* ¶ 16. She accordingly underwent revision in April 2017 to remove the mesh. *Id.* ¶ 17. Her complications from the device have not ceased since its removal. *Id.* ¶ 18.

The Borkensteins have sued largely in product liability. In doing so, they allege that the MiniArc has several defects: use of polypropylene and collagen in the product primarily, but also its other design features of a transvaginal insertion; propensity to shrink, creep, degrade, or fragment (ostensibly terms of art in this industry), its arms and anchors that might injure major nerve routes or invite contamination, and its inelasticity. *Id.* ¶ 49; *see also* ¶¶ 20, 40-45.

Perhaps chief among those design defect theories is that the MiniArc contains monofilament polypropylene mesh and collagen that, as alleged, remain biologically incompatible with human tissue and promote a negative immune response, leading to a host of adverse reactions. *Id.* ¶ 20. The Borkensteins allege that the medical device defendants knew or should have known about the product's risks and complications, including those identified by the FDA, the American College of Obstetricians and Gynecologists, and American Urogynecology Society. *Id.* ¶¶ 22-43. As such, the Borkensteins further allege that the medical device defendants failed to warn patients and healthcare providers adequately about the risks attendant to the MiniArc, articulating some nineteen ways in which the warnings should have been more robust. *Id.* ¶¶ 46-48, 50-51, 56, 62-64.

STANDARD

In reviewing a motion to dismiss under Rule 12(b)(6), the court accepts all well-pleaded factual allegations as true and draws all reasonable inferences in the plaintiff's favor. *Reynolds v. CB Sports Bar, Inc.*, 623 F.3d 1143, 1146 (7th Cir. 2010). A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The statement must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face and raise a right to relief above the speculative level. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A plaintiff's claim must be plausible, not probable. *Indep. Trust Corp. v. Stewart Info. Servs. Corp.*, 665 F.3d 930, 935 (7th Cir. 2012). Evaluating whether a claim is sufficiently plausible to survive a motion to dismiss is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *McCauley v. City of Chicago*, 671 F.3d 611, 616 (7th Cir. 2011) (quoting *Iqbal*, 556 U.S. at 678).

DISCUSSION

A. *The Indiana Products Liability Act Governs A Product Liability Tort Claim under Three Theories.*

The Indiana Products Liability Act (IPLA) governs all tort claims brought by a consumer against a manufacturer for physical harm caused by its product—regardless of legal theory. Ind. Code § 34-20-1-1; *see also Kennedy v. Guess, Inc.*, 906 N.E.2d 776, 779-80 (Ind. 2004); *Kaiser v. Johnson & Johnson*, 2020 U.S. App. LEXIS 1174, 17 (7th Cir. Jan. 14, 2020). A manufacturer who places "into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer . . . is subject to liability for physical harm caused by that product." Ind. Code § 34-20-2-1.

The IPLA recognizes three theories of liability. "A product may be defective under the IPLA if it is defectively designed, if it has a manufacturing flaw, or if it lacks adequate warnings about dangers associated with its use." *Brewer v. PACCAR, Inc.*, 124 N.E.3d 616, 621 (Ind. 2019); *accord Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.3d 953, 956 (Ind. 2018). By its express terms, and since the

1995 amendments, the IPLA grounds design defect and failure to warn theories in negligence terms—requiring a user or consumer to "establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions." Ind. Code § 34-20-2-2; *see also Campbell Hausfeld*, 109 N.E.3d at 957.

In contrast to these two theories, a manufacturing defect theory in Indiana remains grounded in strict liability in the true sense—namely, a showing of negligence is not required. Ind. Code § 34-20-2-2; *see also Kaiser*, 2020 U.S. App. LEXIS 1174 at 17. As with any IPLA theory of product liability, a user or consumer must establish that the product was in a "defective condition unreasonably dangerous" to her. Once established for a manufacturing defect theory, however, that standard applies even though "the seller has exercised all reasonable care in the manufacture and preparation of the product." Ind. Code §§ 34-20-2-1, 34-20-2-2(1).

B. *The Borkensteins May Proceed on Design and Warning Theories under the IPLA, But Not a Manufacturing Defect Theory Per this Second Amended Complaint.*

The medical device defendants initially argue that the second amended complaint contains but conclusory and vague allegations such that they cannot discern, in their words, the "purported defects" that the Borkensteins are advancing in this case. ECF 32 at 3-4. The defendants contend that the sole allegations of fact appear in paragraphs 15-18, with the remaining 118 paragraphs of the pleading serving as boilerplate. This argument is decidedly wrong, and the court will not tarry on it. The second amended complaint provides specific allegations of design and warning defects, as the court has discussed already in summarizing the pleading. *See*, *e.g.*, ECF 34 ¶¶ 20, 22-51, 56, 62-64.

That said, the Borkensteins have not done so under a manufacturing theory. Though the IPLA does not say it, and though the IPLA was originally an outgrowth of Restatement (Second) of Torts § 402A and not the Restatement (Third) of Torts §§ 1-2 published in 1998, certain opinions have required a consumer under the IPLA to show that the product "deviates from its intended design"

based on the Third Restatement's iteration of this claim. *Piltch v. Ford Motor Co.*, 778 F.3d 628, 632-33 (7th Cir. 2015) (citing *Hathaway v. Cintas Corp. Servs.*, 903 F. Supp.2d 669, 673 (N.D. Ind. 2012) and RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(a) (1988)); *cf.* Ind. Code § 34-20-2-1 (standard) and § 34-6-2-146 (defining "unreasonably dangerous"); *Vaughn v. Daniels Co.*, 841 N.E.2d 1133, 1140-42 (Ind. 2006); *accord* RESTATEMENT (SECOND) OF TORTS § 402A cmt. *i* (1965). Although this opinion follows this precedent, albeit with the noted hesitation, the court adds that this standard certainly reflects the modern era of strict liability manufacturing defect claims and underscores the emphasis on manufacturing defect claims in Indiana as based on strict liability, not negligence.

Here, the Borkensteins reiterate the same standard for manufacturing defects in their third count. ECF 34 ¶ 83 (the product "was not reasonably safe for its intended use and was defective . . . with respect to its manufacture, in that it deviated materially from Defendant's design and manufacturing specifications"). That count incorporates the allegations of defect within the second amended complaint—all of which speak to design and warning defects (often expressly—*e.g.*, ECF 34 ¶ 49, alleging "biomechanical issues with the design" and "design of arms and anchors"). The second amended complaint offers no factual explanation how the product deviated materially from its intended design or specifications, should that standard hold under Indiana law for manufacturing defect claims, or alternatively how the product exposed a risk to Ms. Warner-Borkenstein beyond that contemplated by the ordinary consumer precisely because of a manufacturing defect, as the IPLA expressly requires. *See* Ind. Code §§ 34-20-2-1, 34-6-2-146. Indeed, in response to the motion to dismiss, the Borkensteins articulate no theory specific to the build or manufacture of the MiniArc to sustain a manufacturing defect claim. Accordingly, they cannot proceed on this theory based on federal pleading standards, *see Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 570, though discovery may establish a basis for amendment later under Fed. R. Civ. P. 15.

C. *As Pleaded, the Negligence and Gross Negligence Claims Are Subsumed by the IPLA.*

A separate negligence claim also cannot proceed. The Borkensteins reiterate various theories on how the medical device defendants breached the standard of care, and they clarify that they seek recovery under the IPLA and alternatively "common law negligence principles." ECF 34 ¶ 68. Still, the standard of care for product liability tort actions remains the IPLA because of Ms. Warner-Borkenstein's status as a user or consumer vis-à-vis this product. *See Vaughn*, 841 N.E.2d at 1144. There appears to be no other negligence theory in the second amended complaint but as a product user or consumer. Under these circumstances, "the legislature intended that the [IPLA] govern all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 976 (Ind. 2002); *see also Vaughn*, 841 N.E.2d at 1144; *Kennedy*, 906 N.E.2d at 779-80; *Kaiser*, 2020 U.S. App. LEXIS 1174 at 17; *see*, *e.g.*, *Taylor v. Monsanto Co.*, 150 F.3d 806, 808 (7th Cir. 1998) ("no doctrinal distinction between the negligence and strict liability failure-to-warn actions"). The negligence claim in count 1 must accordingly be dismissed.

The gross negligence claim fares no better. There are no degrees of negligence in Indiana. *South E. Ind. Natural Gas Co. v. Ingram*, 617 N.E.2d 943, 953 (Ind. Ct. App. 1993). "The law imposes but one common law duty and that duty is to use due care." *Id.* As such, and particularly as adumbrated, the gross negligence claim in count 13 is likewise subsumed within the IPLA. *See Vaughn*, 841 N.E.2d at 1144. *Stegemoller*, 767 N.E.2d at 976; *see also Fowler v. Werner Co.*, 2014 U.S. Dist. LEXIS 79174, 3 (N.D. Ind. June 10, 2014) (Miller, J.) (same conclusion).

D. *As Pleaded, the Express and Implied Warranty Claims Are Subsumed by the IPLA.*

Likewise, the express and implied warranty claims (counts 6 and 7) cannot survive as pleaded here. To be sure, product liability tort law and contract law remain separate in Indiana under specific circumstances, *see*, *e.g.*, *Hitachi Constr. Mach. Co. v. Amax Coal Co.*, 737 N.E.2d 460, 465 (Ind. Ct. App. 2000) (quoting *B & B Paint Corp. v. Shrock Mfg., Inc.*, 568 N.E.2d 1017, 1020 (Ind. Ct. App. 1991)), but

the claims here sound in product liability and tort. Introducing each claim, the Borkensteins allege precisely that they "seek recovery under Ind. Code Ann. § 34-20-1-1" otherwise "known as the Indiana Products Liability Act" (ECF 34 ¶¶ 92, 100), not the Uniform Commercial Code as adopted in Indiana. *See B & B Paint,* 568 N.E.2d at 1020. They additionally clarify that the basis for each warranty theory is that the product was "unreasonably dangerous and defective," echoing the IPLA. ECF 34 ¶¶ 96, 105; Ind. Code § 34-20-2-1. They also seek punitive damages for these warranty claims, thus indicating that they are not intended to be UCC-based. ECF 34 ¶¶ 99, 107. Alternative pleading is permitted; but, as masters of their pleading, the Borkensteins expressly allege their claims within the confines of the IPLA (*id.* ¶¶ 92, 100), so these claims are subsumed and must be dismissed.

E. *The Borkensteins May Proceed With Their Derivative Consortium Claim and Prayer for Punitive Damages.*

The medical device defendants last argue for the dismissal of the punitive damages request, as well as the loss of consortium claim, but only on the basis that these claims must be dismissed as derivative of the other claims that would be dismissed if the defendants had their way. Because the court has not dismissed the other claims in their entirety, the argument for dismissal of the consortium claim and punitive damages fails.

CONCLUSION

That all said, the court GRANTS and DENIES the motion to dismiss the second amended complaint in part (ECF 31) and DISMISSES counts 1, 3, 6, 7, and 13 of the second amended complaint. The court notes that the second amended complaint voluntarily withdrew counts 5, 8-12, and 14-16 from prior pleadings. Accordingly, the second amended complaint may proceed on the single IPLA cause of action under both design defect and failure to warn theories, as alleged in counts 2 and 4, as well as the derivative loss of consortium claim in count 17. The court DENIES AS MOOT the motion to dismiss the first amended complaint (ECF 19).

SO ORDERED.

January 21, 2020

s/ Damon R. Leichty
Judge, United States District Court